

Notice of Allowability

Application No.

10/628,102

Examiner

Traviss C. McIntosh

Applicant(s)

DUNNE, MICHAEL WILLIAM

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to amendment after final filed May 31, 2005.
2. ☒ The allowed claim(s) is/are 1,9-19,21,27 and 148-179.
3. ☒ The drawings filed on 25 July 2003 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

The application has been amended as follows:

The first paragraph under the title "Single Dose Azithromycin" on page 1 has been deleted and replaced by the following paragraph:

This application is a continuation of US Patent Application Serial No. 10/224,903 filed August 21, 2002, now abandoned, which claims priority to US Patent Application Serial No. 60/313,867 filed August 21, 2001, both of which are hereby incorporated by reference herein in their entireties.

Allowable Subject Matter

Claims 1, 9-19, 21, 27, and 148-179 are allowed.

The prior art does not teach or fairly suggest treating AOM using a single dose of azithromycin of about 40 mg/kg body weight (or about 1.5-4.5 g). It is noted that the closest prior art is seen to be the PSL document and Block et al. (both of record) who both disclose methods of treating AOM using a single dose of 30 mg/kg. One of skill in the art would not be motivated to nor find it obvious to increase the art known amounts of 30 mg/kg by over 33% to thus obtain a dosage of about 40 mg/kg, as in applicant's claims. Moreover, one of ordinary skill

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in the art would not be motivated to nor find it obvious to treat a bacterial respiratory infection with a dose of about 40 mg/kg or greater (or single 2g dose) of azithromycin, wherein the closest prior art is seen to be Schonwald et al. (reference filed in IDS on 10/12/04) who teach treating atypical pneumonia syndrome (a bacterial respiratory infection) with a single 1.5g dose of azithromycin. One of skill in the art would not be motivated to nor find it obvious to increase the art known amounts of 1.5 g by over 33% to thus obtain a dosage of 2g or about 40 mg/kg, as in applicant's claims. The range of "about 40 mg/kg or greater" is not seen to be obvious over the prior art's taught range of "30 mg/kg". Moreover, applicants have shown multiple side by side comparisons in their specification of once a day vs. multiple dosing therapies wherein a single dose is seen to provide unexpectedly better activity than multiple doses which amounted to the same amount as the single dose.

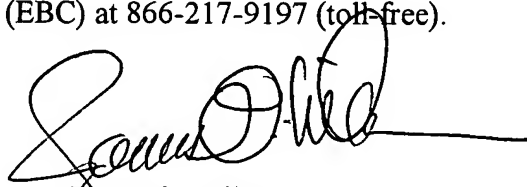
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C. McIntosh whose telephone number is 571-272-0657. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Traviss C. McIntosh III
June 8, 2005



James O. Wilson
Supervisory Patent Examiner
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